United States Surgical Corporation 510(k) Premarket Notification Surgical Dynamics™ Bone Pin\*\*

K970036

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## 510(k) SUMMARY OF INFORMATION:

SUBMITTER:

United States Surgical Corporation

150 Glover Avenue Norwalk, CT 06856 (203) 845-1000

**CONTACT PERSON:** 

Melissa Mazzoni

DATE PREPARED:

December 31, 1996

**CLASSIFICATION NAME:** 

Pin, Fixation, Smooth or threaded metallic bone fixation

fastener

**COMMON NAME:** 

Fixation Pin or Rod

**PROPRIETARY NAME:** 

Trademark name not yet determined.

**DEVICE DESCRIPTION:** 

The Surgical Dynamics™ Bone Pin\*\* is a resorbable fixation pin intended for fixation of small bone fragments in non-load bones with appropriate immobilization. It will be available in a range of sizes and will be supplied

without attached K-wires.

PREDICATE DEVICE:

Poly-Medics Lactosorb® Bone Pin (K953194)

INTENDED USE:

Both the Surgical Dynamics™ Bone Pin\*\* and the Poly-Medics Lactosorb® Bone Pin (K953194) are intended for fixation of small bone fragments in non-load bones with appropriate immobilization.

MATERIALS:

Both the Surgical Dynamics™ Bone Pin\*\* and the Poly-Medics Lactosorb® Bone Pin (K953194) are comprised of

biosafe materials.

Page 11